UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

PFIZER INC., PFIZER LIMITED and PFIZER IRELAND PHARMACEUTICALS, Plaintiffs and Counterclaim Defendants, v. TEVA PHARMACEUTICALS USA, INC., Defendant and Counterclaim Plaintiff.	Civil Action No. 2:10-cv-00128-RBS-FBS

TEVA'S STATEMENT REGARDING ITS MOTION FOR LEAVE TO FILE AN AMENDED ANSWER AND COUNTERCLAIM

Pursuant to the Court's December 13, 2010 instruction after oral argument that "Counsel may file any other pleadings re motion (document #55) [Teva's November 12, 2010 Motion for Leave to File an Amended Answer and Counterclaim ("Motion for Leave to Amend")] by 12:00 noon, on Thursday, December 16, 2010," Teva submits this brief statement about three issues raised during the December 13, 2010 oral argument on Teva's Motion for Leave.

(1) Teva's Claim Of Inequitable Conduct Is Not A Commonplace Boilerplate Assertion Of Misconduct Based On An Alleged Failure To Identify The Work Of Others To The Patent Examiner – Pfizer's Inventor Declared That His Patent Claims Are Invalid

At oral argument, Pfizer attempted to justify its failure to withdraw the application that subsequently issued as U.S. Patent No. 6,469,012 ("the '012 patent") -- after the patent was allowed, but before it issued -- and submit it for continued examination on grounds that a big company like Pfizer cannot be expected to suspend the issuance of one of its U.S. patents each

time a new issue is raised in a proceeding involving a foreign counterpart of that patent. Pfizer also repeatedly characterized the facts underlying Teva's contention of inequitable conduct as boilerplate reflexively asserted to unfairly impugn Pfizer personnel in a hopeless attempt to establish that supposedly disfavored defense.

The facts, however, are highly unusual and far more troubling than those often asserted by litigants as the basis for a claim of inequitable conduct. Unlike any other case to which the parties refer, ***the inventor*** here submitted a sworn affidavit in a foreign proceeding in Canada in which he concluded that his claims directed to the treatment of erectile dysfunction in "animals" are invalid as overbroad. Whitehill Decl. Ex. 3, Ellis Aff. at ¶¶ 59, 60. The inventor also testified that before such claims were disclaimed in Canada, he consulted with Pfizer's attorneys who prosecuted the Canadian application. Whitehill Decl. Ex. 9, 01/16/07 Ellis Depo. at 28:19–33:11. Pfizer has not denied that the Pfizer attorneys prosecuting the '012 patent knew about the overbreadth of the Canadian animal claims before the '012 patent issued. Pfizer's attempt to portray itself as a worthy patentee maligned for a failure to withdraw the '012 patent from issuance merely because of the presentation of a prior art reference in an obscure foreign proceeding is misleading because Pfizer's inventor unequivocally concluded that the animal claims are invalid in light of the arguments first presented by Bayer in the litigation regarding the Canadian counterpart of the '012 patent and withheld that knowledge from the United States Patent and Trademark Office.

Pfizer reiterated its understanding that inequitable conduct defenses are disfavored by the courts and even suggested that the Federal Circuit will disallow or weaken the defense in an upcoming *en banc* opinion in a case pending before it. Pfizer's one-sided view that the Federal Circuit is on the cusp of eliminating inequitable conduct as a defense is unfounded. The Federal

Circuit affirmed findings of inequitable conduct in a number of recent cases including *Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.,* 607 F.3d 817 (Fed. Cir. 2010), *Avid Identification Sys., Inc. v. Crystal Import Corp.*, 603 F.3d 967 (Fed. Cir. 2010) and *Taltech Ltd. v. Esquel Enters. Ltd.*, 604 F.3d 1324 (Fed. Cir. 2010).[1]

(2) Pfizer's Partial Covenant Not To Sue Does Not Obviate Teva's Proposed Defense And Counterclaim That The '012 Patent Is Unenforceable Due To Inequitable Conduct

On December 6, 2010, hours after Teva filed its Reply Brief in support of its Motion for Leave to Amend, Pfizer served Teva with a covenant not to sue Teva for infringement of claims 1-23 of the '012 patent, the so-called "animal" claims that cover use of PDE5 inhibitors in humans, but are not limited to humans.[2] On December 8, 2010, Pfizer filed a Notice of Supplemental Development Concerning Teva's Motion for Leave to File an Amended Answer and Counterclaim ("Notice," D.I. 64), in which Pfizer stated: "[a]fter Teva filed its reply brief, but on the very same day, Pfizer provided Teva with a Covenant Not to Sue on claims 1-23 of the '012 patent, *i.e.*, the animal claims." By filing its Notice in connection with Teva's Motion for Leave to Amend, Pfizer implied to this Court that the covenant not to sue obviates Teva's Motion for Leave to Amend by removing the animal claims from the litigation. As Pfizer's counsel was forced to expressly concede during oral argument, however, the covenant not to sue

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[1] Notably, the Federal Circuit issued each of those decisions ***after*** deciding to reexamine certain issues pertaining to the inequitable conduct standard *en banc* in *Therasense, Inc. v. Becton, Dickinson & Co.*, 374 Fed. Appx. 35 (Fed. Cir. Apr. 26, 2010), the decision referenced by Pfizer's counsel.

[2] Pfizer has not explained why it waited to notify Teva until after Teva filed its Reply Brief. Teva first asked Pfizer for a covenant not to sue for infringement of the animal claims in July 2010. Pfizer's counsel signed the covenant on November 17, 2010, only five days after Teva filed its Motion for Leave to Amend, and the covenant was fully executed on December 1, 2010. The only inference to be reached from Pfizer's conduct is that Pfizer waited

does not obviate the Court's subject matter jurisdiction over Teva's proposed defense and counterclaim for unenforceability of the '012 patent based on Pfizer's inequitable conduct with respect to the animal claims.

It is settled law that "[w]hen a court has finally determined that inequitable conduct occurred in relation to one or more claims during prosecution of the patent application, the entire patent is rendered unenforceable". *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988). Therefore, a covenant not to sue for infringement of only some claims of a patent – a "partial" covenant not to sue – does not divest a court of jurisdiction to determine whether the remaining asserted claims of the patent are unenforceable due to inequitable conduct committed in procuring the claims that are subject to the partial covenant not to sue. *Amgen, Inc. v. Ariad Pharma, Inc.*, 577 F. Supp. 2d 702, 713 (D. Del. 2008) (partial covenant not to sue "does not divest [the Court] of subject matter jurisdiction to hear [the accused infringer's] unenforceability defenses").[3] Thus, notwithstanding Pfizer's belated covenant not to sue, Teva is entitled to prove that Pfizer obtained the animal claims through inequitable conduct, because inequitable conduct with respect to those claims renders unenforceable all claims of the '012 patent", including claims 25 and 26, the claims asserted by Pfizer against Teva.

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to serve the covenant to achieve a tactical advantage in connection with its opposition to Teva's Motion for Leave to Amend.

[3] *See also MedImmune, Inc. v. Genentech, Inc.*, 535 F. Supp. 2d 1000, 1005 n.1 (C.D. Cal. 2008) ("a *partial* covenant not to sue may limit the scope of an invalidity counterclaim but not the scope of an unenforceability counterclaim … A determination that inequitable conduct has occurred renders the entire patent unenforceable" (emphasis in original)).

(3) Pfizer's Covenant Not To Sue Does Not Establish That The Animal Claims 1-23 Are "Meaningless" To Pfizer

Pfizer asserted at oral argument that the covenant not to sue establishes that the animal claims 1-23 of the '012 patent are "meaningless" to Pfizer, *i.e.*, that those claims have no commercial value with respect to Pfizer's monopoly over treatments for erectile dysfunction. That assertion is wrong because the covenant not to sue Teva does not prevent Pfizer from asserting claims 1-23 against another party. In fact, claims 1-23 potentially are of great monopoly value to Pfizer because they are directed to methods of treating male humans suffering from erectile dysfunction with untold thousands of compounds not covered by asserted human claims 25 and 26 by any means of administration, not merely oral administration to which claims 25 and 26 are limited. If those overbroad animal claims truly were of no value, then Pfizer simply would have disclaimed those claims or dedicated them to the public – it has not done so.[4] Pfizer's belated execution of a covenant not to sue Teva for infringement of the animal claims and its argument that those claims are "meaningless" is a misleading attempt to shield those claims from the Court's scrutiny of their validity and enforceability, while preserving Pfizer's option to assert them against others.

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[4] During oral argument, Pfizer presented a new theory that the animal claims are "meaningless" on grounds that they are no broader than claim 20, which is limited to the treatment of humans and depends from claim 6, which in turn depends from claim 1. Pfizer's new theory is demonstrably wrong. The scope of claim 20 is not nearly as broad as the broadest animal claims because claim 20 is limited to oral administration of the claimed compounds whereas many of the animal claims, which also cover humans, do not limit the route of administration, and therefore cover other forms of administration, such as intravenous, sublingual or buccal administration. Whitehill Decl. Ex. 1, '012 patent claims 5, 21, 22. The specification of the '012 patent leaves no doubt that Pfizer valued such other forms of administration, as it expressly states in one of its few substantive disclosures: "[i]n circumstances where the recipient suffers from a swallowing disorder or from impairment of drug absorption after oral administration, the drug may be administered parenterally, e.g. sublingually or buccally." *Id*. at 5:66-6:3.

Dated: December 16, 2010

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CERTIFICATE OF SERVICE

I hereby certify that on the 16th day of December, 2010, I will electronically file the foregoing *Teva's Statement Regarding Motion for Leave to File an Amended Answer and Counterclaim* using the CM/ECF system, which will then send a notification of such filing to the following counsel of record:

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